MAY 3 2006

K 060585

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250
(317)-521-3532

Contact person: Randy J. Johnson

Date Prepared: March 6, 2006

Device Name

Proprietary name:
(1) Elecsys ACTH Immunoassay
(2) Elecsys ACTH CalSet
(3) Elecsys ACTH CalCheck
(4) Elecsys PreciControl ACTH

Common name:
(1) ACTH Assay
(2) ACTH CalSet
(3) ACTH CalCheck
(4) PreciControl ACTH

Classification name:
(1) System, Test, ACTH
(2) Calibrator, Secondary
(3 & 4) Single (specified) analyte controls (assayed and unassayed)

510(k) Summary, Continued

Device Description

(1) The Elecsys ACTH Assay is a two step sandwich immunoassay with streptavidin microparticles and electrochemiluminescence detection. Results are determined using a calibration curve that is generated specifically on each instrument by a 2 point calibration and a master curve provided with the reagent bar code.
(2) The Elecsys ACTH CalSet is a lyophilized product consisting of equine serum with added ACTH in two concentration range. During manufacture, the analyte is spiked into the matrix at the desired concentration levels.
(3) The Elecsys ACTH CalCheck is a lyophilized product consisting of buffered equine serum with added ACTH. During manufacture, the analyte is spiked into the matrix at the desired concentration levels.
(4) The Elecsys PreciControl ACTH is a lyophilized product consisting of equine serum with added ACTH in two concentration ranges. During manufacture, the analyte is spiked into the matrix at the desired concentration levels.
Note: The reagent, calibrator, calibration verification material and the quality control are all packaged separately.

Intended use

(1) Elecsys ACTH Reagent: Immunoassay for the in vitro quantitative determination of adrenocorticotropic hormone (ACTH) in human EDTA plasma. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Roche Elecsys 1010/2010 and MODULAR ANALYTICS E 170 (Elecsys module) immunoassay analyzers.

(2) Elecsys ACTH CalSet is used for calibrating the quantitative Elecsys ACTH assay on the Elecsys immunoassay analyzers.

(3) Elecsys ACTH CalCheck: For use in the verification of the calibration established by the Elecsys ACTH reagent on Elecsys 1010/2010 and MODULAR E170 immunoassay analyzers.

(4) Elesys PreciControl ACTH is used for quality control of the Elecsys ACTH immunoassay on the Elecsys immunoassay analyzers.

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510(k) Summary, Continued

Indications for Use

(1) Elecsys ACTH Reagent: Immunoasssay for the in vitro quantitative determination of adrenocorticotropic hormone (ACTH) in human EDTA plasma. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Roche Elecsys 1010/2010 and MODULAR ANALYTICS E 170 (Elecsys module) immunoassay analyzers. ACTH measurments are used in the differential diagnosis and treatment of certain disorders of the adrenal glands such as Cushings syndrome, adrenocortical insufficiency, and the ectopic ACTH syndrome.

(2) Elecsys ACTH CalSet is used for calibrating the quantitative Elecsys ACTH assay on the Elecsys immunoassay analyzers.

(3) Elecsys ACTH CalCheck: For use in the verification of the calibration established by the Elecsys ACTH reagent on Elecsys 1010/2010 and MODULAR E170 immunoassay analyzers.

(4) Elesys PreciControl ACTH is used for quality control of the Elecsys ACTH immunoassay on the Elecsys immunoassay analyzers.

Substantial equivalence

The Elecsys ACTH Test System is substantially equivalent to other devices legally marketed in the United States.

(1) Elecsys ACTH Immunoassay is equivalent to the Immulite ACTH assay (K960066). Both products are intended for use in the quantitative determination of ACTH in plasma.

(2) Elecsys ACTH CalSet is equivalent to the Immulite ACTH assay (K960066).

(3) Elecsys ACTH CalCheck is equivalent to the Elecsys Prolactin II CalCheck (K053059).

(4) Elecsys PreciControl ACTH is equivalent to the Elecsys PreciControl Troponin T (K031990).

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510(k) Summary, Continued

Substantial equivalence – similarities

Immunoassay Comparison		
Feature	**Elecsys ACTH**	**Predicate Device Immulite ACTH Assay**
Intended Use	Immunoassay for the in vitro quantitative determination of adrenocorticotropic hormone (ACTH) in human EDTA plasma. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Roche Elecsys 1010/2010 and MODULAR ANALYTICS E 170 (Elecsys module) immunoassay analyzers.	For in vitro diagnostic use with the Immulite 2000 analyzer – for the quantitative measurement of adrenocorticotropic hormone in EDTA, plasma, as an aid in the assessment of adrenal insufficiency and hypersecretion
Indication for Use	ACTH measurements are used in the differential diagnosis and treatment of certain disorders of the adrenal glands such as Cushings syndrome, adrenocortical insufficiency, and the ectopic ACTH syndrome.	As an aid in the assessment of adrenal insufficiency and hypersecretion.
Assay Protocol	Sandwich assay	Solid-phase, two site
Detection Protocol	Electrochemiluminescent Immunoassay	Chemiluminescent immunometric assay
Sample Type	Human plasma treated with K_3-EDTA	Human plasma treated with EDTA
Calibrator	ACTH CalSet	ACTH Adjustors (LACL, LACH)

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510(k) Summary, Continued

Substantial equivalence – similarities, continued

CalSet Comparison		
Characteristic	**Elecsys ACTH CalSet**	**Predicate Device Immulite ACTH Assay**
Intended Use	Used for calibrating the quantitative Elecsys ACTH assay on the Elecsys immunoassay analyzers.	N/A
Levels	Two	Same
Format	Lyophilized	Same
CalCheck Comparison		
Characteristic	**Elecsys ACTH CalCheck**	**Predicate Device Elecsys Prolactin II CalCheck**
Levels	Three	Same
Format	Lyophilized	Same
Stability	Unopened: Store at 2-8°C up to the printed expiration date on the bottle labels Reconstituted: 15 – 25 °C : 4 hrs	Same
PreciControl Comparison		
Characteristic	**Elecsys ACTH PreciControl**	**Predicate Device Elecsys PreciControl Troponin T**
Levels	Two	Same
Format	Lyophilized	Same
Handling	Dissolve carefully the contents of one bottle by adding exactly 2.0 mL of distilled water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding the formation of foam.	Same

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510(k) Summary, Continued

Substantial equivalence – differences

Immunoassay Comparison		
Feature	**Elecsys ACTH**	**Predicate Device Immulite ACTH Assay**
Traceability / Standardization	Standardized gravimetrically with synthetic ACTH produced at Roche.	N/A
Calibration Interval	E170/Elecsys 2010: After 1 month (28 days) when using the same reagent lot. After 7 days (when using the same reagent kit on the analyzer). Elecsys 1010: With every reagent kit. After 7 days (20-25°C). After 3 days (25-32°C).	Every four weeks.
Platform	Roche Elecsys 1010/2010 and MODULAR ANALYTICS E170 (Elecsys module) analyzers.	Immulite 2000 Analyzer
Calibration Verification	ACTH CalCheck	None stated in the package insert.
Controls	PreciControl ACTH	LACCM: Bi-level ACTH control module (protein based)..
Reagent Stability	Unopened: 2-8°C - Up to the stated expiration date Opened: 2-8°C - 12 weeks On the E170 / Elecsys 2010 – 4 weeks On the Elecsys 1010: – 4 weeks (stored alternately in the refrigerator and on the analyzer- ambient temperature 20-25°C; up to 20 hours opened in total.)	ACTH Reagent Wedge: Stable at 2 – 8°C until the expiration date.
Measuring Range	1 – 2,000 pg/mL	5 – 1,250 pg/mL

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510(k) Summary, Continued

Substantial equivalence – differences

Immunoassay Comparison		
Feature	**Elecsys ACTH**	**Predicate Device Immulite ACTH Assay**
Precision	*Elecsys 1010/2010:* Within-run 2.9% CV @ 4.9 pg/mL 2.0% CV @ 74.2 pg/mL 2.1% CV @ 1,390 pg/mL 1.5% CV @ 115 pg/mL 1.6% CV @ 970 pg/mL Total 5.4% CV @ 4.9 pg/mL 2.4% CV @ 74.2 pg/mL 2.6% CV @ 1,390 pg/mL 1.7% CV @ 115 pg/mL 1.8% CV @ 970 pg/mL *E170:* Within-run 2.7% CV @ 4.9 pg/mL 0.6% CV @ 64.3 pg/mL 0.7% CV @ 1,205 pg/mL 0.6% CV @ 111 pg/mL 1.2% CV @ 968 pg/mL Total 5.4% CV @ 4.96 pg/mL 3.5% CV @ 76.1 pg/mL 3.7% CV @ 1,444 pg/mL 1.8% CV @ 114 pg/mL 2.0% CV @ 972 pg/mL	Intra-assay: 8.7% CV @ 23 pg/mL 6.7% CV @ 30 pg/mL 6.8% CV @ 40 pg/mL 6.9% CV @ 208 pg/mL 9.5% CV @ 421 pg/mL Interassay: 10.0% CV @ 24 pg/mL 8.2% CV @ 44 pg/mL 8.7% CV @ 89 pg/mL 9.3% CV @ 229 pg/mL 6.1% CV @ 496 pg/mL
Analytical sensitivity (LDL)	1.0 pg/mL	5 pg/mL

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510(k) Summary, Continued

Substantial equivalence – differences

Immunoassay Comparison		
Feature	**Elecsys ACTH**	**Predicate Device Immulite ACTH Assay**
Method Comparison (Linear Regression)	Elecsys ACTH (y) versus a commercially available ACTH test (x): y= 0.90x + 8.17, r = 0.992, n=180	DPC Immulite 2000 versus DPC Immulite: (IML 2000) = 0.95 (IML) + 2.9 pg/mL r = 0.988, n = 86
Analytical Specificity	No cross reactivity for: ACTH (1-10) ACTH (11-24) Beta MSH Beta Endorphin ACTH fragments: (ACTH 1-17, ACTH 1-24, ACTH CLIP 18-39, ACTH 22-39, Alpha MSH 1-13) > 5,000 pg/mL can bind to one of the antibodies and thereby negatively interfere with the sandwich formation and lead to lower ACTH values. Under ACTH (1-24) medication, ACTH measurement is not recommended. POMC (partially purified from an adenoma cell line) showed an approximate 1.6% cross-reactivity at 1,560 pmol/L which is approximately forty times the physiological concentration of ACTH precursors in circulation.	No cross reactivity for: ACTH (1-18) Cross reactivity: ACTH (1-24) ACTH (18–39) Alpha MSH
Hook Effect	No high dose hook effect up to 1,000,000 pg/mL	No high dose hook effect up to 1,500,000 pg/mL

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510(k) Summary, Continued

Substantial equivalence – differences

Immunoassay Comparison		
Feature	**Elecsys ACTH**	**Predicate Device Immulite ACTH Assay**
Limitations	The assay is unaffected by: • Icterus (bilirubin <428 µmol/L or <25 mg/dL • Hemolysis (<0.25 mmol/L or <0.4 g/dL) • Lipemia (Intralipid < 1,500 mg/dL) • Biotin (<246 nmol/L or , 60 ng/mL) • In patients receiving therapy with high biotin doses (i.e > 5 mg/day), no sample should be taken until at least 8 hours after the last biotin administration • No interference was observed from rheumatoid factors up to a concentration of 400 IU/mL • In vitro tests were performed on 17 commonly used pharmaceuticals. No interference was found with the assay • Under ACTH 1-24 medication, ACTH measurement is not recommended, due to negative interference with the sandwich assay	The assay is unaffected by: • Bilirubin: (Up to 200 mg/L) • Hemolysis: (Up to 512 mg/dL) • Lipemia: (Triglycerides up to 5,000 mg/dL) • Heterophilic antibodes in human serum can react with the immunoglobulins included in the assay components causing interference with in vitro immunoassays. Samples from patients routinely exposed to animals or animal serum products can demonstrate this type of interference potentially causing an anomalous result. These reagents have been formulated to minimize the risk of interference, however, potential interactions between rare sera and test components can occur.

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510(k) Summary, Continued

Substantial equivalence – differences

Immunoassay Comparison		
Feature	**Elecsys ACTH**	**Predicate Device Immulite ACTH Assay**
Limitations	• Erroneous findings may be obtained from samples taken from patients who have been treated with monoclonal antibodies or have received them for diagnostic purposes. • In rare cases, interference due to extremely high titers of antibodies to ruthenium can occur. Elecsys ACTH contains additives which minimize these effects. • Extremely high titers of antibodies to streptavidin can occur in isolated cases and cause interference. • For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings	• For diagnostics purposes, the results obtained from this assay should always be used in combination with the clinical examination, patient medical history, and other findings.

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510(k) Summary, Continued

Substantial equivalence – differences

CalSet Comparison		
Characteristic	**Elecsy ACTH CalSet**	**Predicate device Immulite ACTH Assay**
Matrix	Equine serum	Bovine protein-based
Stability	Unopened: • Store at 2-8°C until expiration date. Reconstituted or thawed: • 2-8°C: 1 week • -20°C: 3 months (freeze only once) • on Elecsys 1010/2010 at 20-25°C: Up to 5 hours • on E170: Use only once	Reconstituted: • -20°C: 2 months
Handling	Dissolve carefully the contents of one bottle by adding exactly 1.0 mL of distilled water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding the formation of foam.	Reconstitute each vial with 4.0 mL distilled or deionized water. Let stand for 30 minutes, then mix by gentle swirling or inversion.

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510(k) Summary, Continued

Substantial equivalence – differences

CalCheck Comparison		
Characteristic	**Elecsys ACTH CalCheck**	**Predicate device Elecsys Prolactin II CalCheck**
Intended Use	For use in the verification of the calibration established by the Elecsys ACTH reagent on Elecsys 1010/2010 and MODULAR E170 immunoassay analyzers.	For use in the verification of the calibration established by the Elecsys Prolactin II reagent on Elecsys 1010/2010 and MODULAR ANALYTICS E170 immunoassay analyzers.
Matrix	Buffered equine serum with synthetic 1-39 ACTH.	Buffered equine serum with recombinant human Prolactin from E. Coli
Handling	Reconstitute the contents with exactly 2.0 mL distilled water or deionized water. Allow the bottle to stand closed for 15 minutes. Mix by inversion to ensure homogeneity.	Reconstitute the contents with exactly 1.0 mL distilled or deionized water. Allow the bottle to stand closed for 15 minutes. Mix by inversion to ensure homogeneity.
Traceability	Standardized gravimetrically with synthethic ACTH produced at Roche.	Standardized against the 3rd IRP WHO Reference Standard 84/500.

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510(k) Summary, Continued

Substantial equivalence – differences

CalCheck Comparison		
Characteristic	**Elecsys ACTH CalCheck**	**Predicate device Elecsys Prolactin II CalCheck**
Intended Use	For use in the verification of the calibration established by the Elecsys ACTH reagent on Elecsys 1010/2010 and MODULAR E170 immunoassay analyzers.	For use in the verification of the calibration established by the Elecsys Prolactin II reagent on Elecsys 1010/2010 and MODULAR ANALYTICS E170 immunoassay analyzers.
Matrix	Buffered equine serum with synthetic 1-39 ACTH.	Buffered equine serum with recombinant human Prolactin from E. Coli
Handling	Reconstitute the contents with exactly 2.0 mL distilled water or deionized water. Allow the bottle to stand closed for 15 minutes. Mix by inversion to ensure homogeneity.	Reconstitute the contents with exactly 1.0 mL distilled or deionized water. Allow the bottle to stand closed for 15 minutes. Mix by inversion to ensure homogeneity.
Traceability	Standardized gravimetrically with synthethic ACTH produced at Roche.	Standardized against the 3rd IRP WHO Reference Standard 84/500.

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510(k) Summary, Continued

Substantial equivalence – differences

PreciControl Comparison		
Characteristic	**Elecsy PreciControl ACTH**	**Predicate Device Elecsys PreciControl Troponin T**
Intended Use	Used for quality control of the Elecsys ACTH immunoassay on the Elecsys immunoassay analyzers.	Used for quality control of the Elecsys Troponin T (Cardiac T) immunoassay on the Elecsys immunoassay systems.
Matrix	Equine serum with added synthetic ACTH	Troponin T (recombinant, human) in human serum
Stability	Unopened: Store at 2-8°C up to the stated expiration date Reconstituted: On the analyzer at 20 - 25°C: Up to three hours. -20 °C : One month (freeze only once) After thawing: Use only once.	Unopened: Store at 2-8°C up to the stated expiration date Reconstituted: On the analyzer at 20 - 25°C: Up to five hours. -20 °C : Three months (freeze only once) After thawing: Use only once. At 2-8°C: Two weeks

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 3 2006

Randy Johnson MT (ASCP)
Regulatory Affairs Consultant
Roche Diagnostics
9115 Hague Road
PO Box 50416
Indianapolis, IN 46250-0416

Re: k060585
Trade/Device Name: Elecsys ACTH Test System
Regulation Number: 21 CFR§862.1025
Regulation Name: Adrenocorticotropic hormone (ACTH) test system
Regulatory Class: Class II
Product Code: CKG, JIT, JJX
Dated: March 6, 2006
Received: March 7, 2006

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060585

Device Name: Elecsys ACTH Test System

Indications For Use:

Elecsys ACTH Assay:
Immunoasssay for the in vitro quantitative determination of adrenocorticotropic hormone (ACTH) in human EDTA plasma. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Roche Elecsys 1010/2010 and MODULAR ANALYTICS E 170 (Elecsys module) immunoassay analyzers. ACTH measurements are used in the differential diagnosis and treatment of certain disorders of the adrenal glands such as Cushings syndrome, adrenocortical insufficiency, and the ectopic ACTH syndrome.

Elecsys ACTH CalSet is used for calibrating the quantitative Elecsys ACTH assay on the Elecsys immunoassay analyzers.

Elecsys ACTH CalCheck:
For use in the verification of the calibration established by the Elecsys ACTH reagent on Elecsys 1010/2010 and MODULAR E170 immunoassay analyzers.

Elecsys PreciControl ACTH is used for quality control of the Elecsys ACTH immunoassay on the Elecsys immunoassay analyzers.

Prescription Use **XXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K060585